

REMARKS

Claims 1-27 are pending in the application. Claims 1-21 stand withdrawn from consideration. Claim 22 has been amended to recite a catheter deflection assembly having a pair of tension/compression members as recited in canceled claim 23. Claims 24, 26 and 27 have been amended to depend from claim 22 instead of canceled claim 23, and claim 25 has been amended to depend from claim 24 instead of claim 22.

Applicant has added new claims 28-35. Support for new claims 28-35 can be found in the specification as a whole. For example, support for new claim 28 can be found at page 7, lines 16-23. Support for new claim 29 can be found at, for example, page 9, lines 15-24 and in Figure 6, and support for new claim 30 can be found in Figure 7. Support for new claims 31 -35 can be found at, for example, page 6, line 3 to page 7, line 7.

Paragraph 31 of the specification was amended to correct the reference numbers, as requested by the Examiner.

Figure 1 of the drawings was amended to add reference number 40, as requested by the Examiner.

No new matter enters by these amendments.

Objections to the Specification

The Examiner objects to the specification because “the term ‘sleeve’ used in the claims lacks antecedent basis in the specification.” Office action, at 4. Applicant is unclear as to the basis for this objection and requests clarification. The statute provides that the specification must contain a written description “in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the invention.” 35 U.S.C. § 112. Applicant submits that based on the specification as a whole a person

of skill in the art would understand what is meant by the term sleeve as used in the claims. For example, the specification provides that “[a]n elongated conduit means 130 is sleeved over the entire length of the tension/compression members except over the flattened portions thereof.” Specification, at page 8, lines 23-24. A conduit is defined as a protective covering, which is a sleeve. See MSN Encarta Online Dictionary (attached). In addition, Figure 2 depicts an inner guide tube 130 covering a pair of tension/compression members 102, 104. A sleeve is a type of tube. See Merriam-Webster Online Dictionary (attached) (defining sleeve as “a tubular part … designed to fit over another part”). Based on the foregoing, Applicant submits that the specification describes a sleeve or conduit means 130 in a manner that clearly establishes the Applicant was in possession of the claimed subject matter at the time the application was filed. Accordingly, Applicant respectfully requests withdrawal of this objection.

The Examiner also objects to the specification because the reference to “102, 104” at page 7, line 9 should refer to reference numerals 62 and 64. Applicant agrees and has amended the specification as suggested by the Examiner. Applicant respectfully requests withdrawal of this objection.

Objection to the Drawings

The Examiner objects to the drawings because they do not include reference numeral 40. A Replacement Sheet for Figure 1 is provided showing reference numeral 40, which identifies the curved configuration at the distal end of the catheter.

The specification describes reference numeral 40 as a curved configuration, such as a loop or lariat, at the distal portion of the catheter. See page 4, line 27 to page 5, line 3. The specification also refers to reference numeral 40 to describe the position of the curved configuration when it is fully deflected or nodded. See page 5, lines 15-20. A person of skill in the art would immediately identify reference numeral 40 as shown on

the attached Replacement Sheet as the curved configuration in its fully deflected position. Applicant submits that no new matter enters by this amendment.

Accordingly, Applicant requests withdrawal of this objection.

Rejections Under 35 U.S.C. § 102(e)

Claim 22 stands rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Bowe (U.S. Pat. 7,013,169). Applicant notes that claim 22 has been amended to recite a catheter deflection assembly having a pair of tension/compression members.

Bowe does not disclose each and every element of amended claim 22. For example, the steering mechanism in Bowe has a single wire attached to an anchor member. See Bowe col. 4, lines 57-62. Bowe does not explicitly or inherently disclose a deflection assembly having a pair of tension/compression members.

For at least this reason, Applicant respectfully requests withdrawal of this rejection.

Claim 22 stands rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Chen (U.S. Pat. 6,671,533). Applicant notes that claim 22 has been amended to recite a catheter deflection assembly having a pair of tension/compression members.

Chen also does not disclose each and every element of claim 22. For example, the steering mechanism described in Chen includes a steering wire attached to an anchor and a flat wire attached to the steering wire. Chen col. 4, lines 45-61. Chen does not explicitly or inherently disclose a deflection assembly having a pair of tension/compression members. As described in Chen, "the flat wire is attached to the steering wire at the distal ends of the flat wire and the steering wire so as to be controlled by the steering wire." Chen col. 4, lines 59-61. It is clear that moving the

steering wire in one direction moves the flat wire in the same direction. In the instant invention, however, "moving the first actuator places one of the members in tension and simultaneously places the other member in compression." See specification page 7, lines 11-12 and page 7, line 30 to page 8, line 4. A person of ordinary skill in the art would understand that the steering wire/flat wire combination of Chen is not a pair of tension/compression members as recited in the present claims.

Accordingly, Applicant respectfully requests withdrawal of this rejection.

Rejections Under 35 U.S.C. § 103

Claims 22-27 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rashidi (U.S. Pat. 6,728,563) in view of Stevens-Wright (U.S. Pat. 5,383,852) and Bowe. Applicant respectfully disagrees and requests withdrawal of this rejection.

Applicant notes that claim 22 has been amended to recite a catheter deflection assembly having a pair of tension/compression members. Claim 22 has also been amended to clarify that the first actuator is operable upon movement to selectively effect lateral displacement of the catheter *from a point proximal to* the curved configuration of the distal portion.

The initial burden is on the Examiner to establish a *prima facie* case of obviousness "by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988); MPEP 2143.01. "[E]ither the references must expressly or impliedly suggest the claimed combination or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Int. 1985). Applicant respectfully submits that the Examiner has

not demonstrated that a person of skill in the art would have been motivated to combine the references in the suggested manner.

The Examiner asserts that it would have been obvious to modify Rashidi in view of Stevens-Wright by adding a second displacement assembly and to further modify Rashidi in view of Bowe by adding a preformed curve at the distal end. Office action, at 3. Applicant respectfully disagrees. Neither Stevens-Wright nor Rashidi describes a catheter having a distal end being preformed into a curved configuration. Bowe discusses a catheter having a preformed curved configuration at the distal end, but it does not discuss or suggest a deflection assembly having a pair of tension/compression members. No objective reason to combine these specific aspects distilled from these documents exists. In fact, Stevens-Wright teaches away from the use of a preformed curve and states that the use of a catheter having a preformed shape is "not very practical, and not helpful in reaching sites requiring active articulation during placement." Stevens-Wright col. 1, lines 39-51. Stevens-Wright further states that a disadvantage of a catheter having a preformed tip is that it "may be steered only in a prescribed manner which cannot be altered during its placement." Stevens-Wright, col. 1, lines 61-68. Based on this disclosure, a person of skill in the art would not be expected to combine any preformed curved configuration with any teaching of Stevens-Wright.

Applicant respectfully asks the Examiner to identify where in the cited documents there is objective evidence of a motivation or suggestion to combine the references to arrive at the claimed invention. Applicant respectfully contends that the Office action cites only conclusory statements regarding obviousness.

Applicant respectfully submits that the Examiner has impermissibly used hindsight to piece together elements of the cited art in rejecting the claims for obviousness. "It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to '[use] that which the inventor taught against its teacher.'" *In re Sang-Su Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002)

(quoting *W.L. Gore v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)). Almost all inventions arise from a combination of old elements; however, it is improper to reject a claim as obvious by simply identifying the elements of an invention in various references without “explain[ing] what specific understanding within the knowledge of one of ordinary skill in the art would have suggested the combination.” *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). The Office action does not point to anything that would have explicitly or impliedly suggested to a person of skill in the art at the time the application was filed that Stevens-Wright and Bowe could be used to modify Rashidi in the proposed manner to arrive at the present invention.

Furthermore, Stevens-Wright and Bowe do not discuss a pair of tension/compression members having a generally flattened transverse portion adjacent the distal end, as recited in dependent claim 24, or a generally circular cross-section of the remaining portion of the pair of tension/compression members as recited in dependent claim 25. Nor do Stevens-Wright and Bowe discuss an elongated sleeve extending over the tension/compression members as recited in dependent claim 27.

Without an objective reason to combine the alleged teachings, a *prima facie* case of obviousness has not been made. Accordingly, Applicant requests withdrawal of this rejection.

Claims 23-27 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chen in view of Rashidi. Applicant respectfully disagrees and requests withdrawal of this rejection. Applicant notes that claim 23 has been canceled, and the recitation of a pair of tension/compression members has been inserted into independent claim 22.

Chen describes a catheter having a preformed curve and an expandable balloon at the distal portion of the catheter, and a steering mechanism for deflecting the catheter distal portion from a point proximal of the expandable balloon. The steering mechanism

of Chen includes a single steering wire attached to an anchor. The Examiner asserts that it would have been obvious to a person of skill in the art to modify Chen by using the deflection mechanism disclosed in Rashidi. Office action, at 4. Applicant respectfully disagrees.

The Examiner has not demonstrated that a person of skill in the art would have been motivated to combine the references in the suggested manner. There is nothing in Chen or Rashidi that expressly or impliedly teaches the modification suggested by the Examiner. The deflection mechanism in Chen utilizes a single steering wire, and nothing in Chen suggests or teaches the use of a catheter deflection assembly having a pair of tension/compression members extending through the casing to selectively effect lateral displacement of the catheter from a point proximal to the curved configuration of the distal portion.

Further, Rashidi describes the use of a tension/compression assembly for deflecting the distal portion of the catheter from a point distal of a preformed bend to form, for example, a halo or lariat configuration. See Rashidi Figs. 1a-1c. Rashidi does not suggest the use of a tension/compression assembly for deflecting the catheter from a point proximal to the preformed bend, as recited in the present claims. Thus, at the time the application was filed, a person of skill in the art would not have been motivated to modify Chen in view of Rashidi to arrive at the claimed invention.

The problem addressed by Chen is providing a system for mapping and ablating tissue inside the pulmonary veins without blocking blood flow. Thus, the preformed shape of the distal ring "functions to anchor the distal tip section inside the PV at the desired location so that the ablation can be performed accurately." Chen col. 6, lines 16-18. The ablation is performed using an ultrasound transducer that is placed inside an inflatable balloon, which is located at some distance proximal of the curved configuration. See Chen Fig. 8. The present invention provides a device for ablating tissue having additional bending capabilities to better control movement of the curved configuration of the distal end. See specification page 3, lines 11-15. The Examiner

has not identified any objective evidence in Chen that would have suggested to a person of skill in the art at the time of filing to modify Chen in view of Rashidi to arrive at the claimed invention. Clearly the type of ablation Chen proposes and the purpose for the preformed configuration differs from the present invention. A person of skill in the art would understand that the use of a preformed curved configuration for anchoring is different from the use of bending up to 180 degrees.

Furthermore, the preformed curved configuration of the Chen catheter does not have the same range of motion as the preformed curved configuration of the present invention, which can deflect bi-directionally and up to 180 degrees, as recited in dependent claims 29 and 30, to permit greater control of the distal portion of the catheter.

In rejecting the claims for obviousness, the Examiner has impermissibly used hindsight to piece together elements of the cited references. Applicant respectfully submits that there is no objective evidence in the cited references of a motivation to combine the references; therefore, the Examiner has impermissibly used hindsight reconstruction to reject the claims.

For the foregoing reasons, Applicant respectfully requests withdrawal of the rejection.

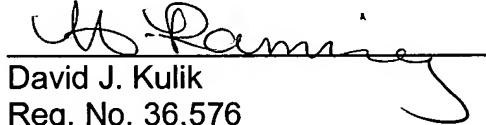
Application No. 10/784,511
Office Action dated October 11, 2006
Response dated February 7, 2007

The application is in condition for allowance. Timely notification of allowability is requested.

If there are any additional fees due with the filing of this document, including fees for the net addition of claims, applicants respectfully request that any and all fees be charged to Deposit Account No. 50-1129. If any additional extension of time request or any petition is required for the entry of this paper or any of the accompanying papers, applicants hereby petition or request the extension necessary. The undersigned authorizes any fee payment from Deposit Account No. 50-1129.

Respectfully submitted,
Wiley Rein LLP

Date: February 7, 2007



David J. Kulik
Reg. No. 36,576
Heather H. Ramirez
Reg. No. 57,369

WILEY REIN LLP
Attention: Patent Administration
1776 K Street, N.W.
Washington, D.C. 20006
Telephone: 202.719.7000
Facsimile: 202.719.7049

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Amendments to the Drawings:

Please replace Sheet 1/2, Figure 1, with the enclosed Replacement Sheet.

sleeve

5 entries found.

sleeve
cap sleeve
dolman sleeve
flutter sleeve
raglan sleeve

Main Entry: **sleeve** 

Pronunciation: \slēv\

Function: *noun*

Etymology: Middle English *sleve*, from Old English *slīfe*; perhaps akin to Old English *slēfan* to slip (clothes) on, *slūpan* to slip, Old High German *slifan*, Latin *lubricus* slippery

Date: before 12th century

1 **a** : a part of a garment covering an arm **b** : SLEEVELET

2 **a** : a tubular part (as a hollow axle or a bushing) designed to fit over another part

b : an open-ended flat or tubular packaging or cover; *especially* : JACKET 3c(2)

— **sleeved**  \slēvd\ *adjective*

— **sleeve-less**  \slēv-ləs\ *adjective*

— **on one's sleeve** : in an honest and open manner — used with *wear* <*wears his emotions on his sleeve*>

— **up one's sleeve** : held secretly in reserve <*has a few tricks up her sleeve*>

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